

Office of Research

Institutional Animal Care and Use Committee

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE August 6, 2020 Teleconference

The August 6, 2020 meeting of the University of South Carolina Institutional Animal Care and Use Committee (IACUC) was called to order by Shannon Davis, Chair, at 3:01 pm.

Committee Members Present:

Dr. Shannon Davis Dr. Shayne Barlow Committee Member IA Committee Member 86 Committee Member 125 Committee Member 147 Committee Member 52 Committee Member 128 Committee Member 91 IACUC Chair Attending Veterinarian

*late arrival **early departure ***non-voting

I. APPROVAL OF MINUTES

A. The committee voted 9-0 to approve the July Minutes

II. CHAIRMAN'S ANNOUNCEMENTS

III. ATTENDING VETERINARIAN'S ANNOUNCEMENTS

- A. FOIA request. As noted last month, UofSC received a FOIA request from NAEVS (New England Anti-Vivisection Society) for our AAALAC Program Description. A redacted copy was sent last week.
- *B.* Furlough issues. Dr. Barlow will take two weeks of University-mandated furlough in December. During this time, no veterinary reviews can be performed. *(See Other Business for follow-up discussion.)*

IV. IACUC ADMINISTRATOR'S ANNOUNCEMENTS

- A. Semi-annual Inspection and Program Review. The Program Review was completed prior to this meeting. Due to COVID-19 concerns, the semi-annual inspections will be conducted by the AV and the IA/VC; dates and times will be provided to the committee so additional members may attend.
- B. PHS Assurance. The draft Assurance was submitted to OLAW on July 6; it has not yet been returned.
- C. OHSP. Active animal users OHSP evaluation were due during the UofSC shutdown and phase-in periods have been notified to complete them by the end of September. The IACUC office is looking into virtual and site-specific assessments to assist users in getting up to date.
- D. USC Aiken has filed for a separate Assurance with OLAW. Once approved, the current protocol for this campus will be terminated.

V. OLD BUSINESS

VI. NEW BUSINESS

A. Annual Reviews

1. Renewals	
2424-101227-082218 (2)	In Review.
2421-101335-081318	Approval Pending.
2422-101348-081318	In Review.
2462-101413-081619	In Review.
2465-101440-082819	Approval Pending.
2461-101448-081419	In Review.
2463-101452-082619	In Review.
2467-101451-090319	In Review.

2. Terminations

2423-101351-082218	No Response from the PI; administrative termination.
2460-101443-080719	No Response from the PI; administrative termination.

B. New Administrative Action 1. Pending Amendments

2407-101317-022118	In Review.
2434-101342-110518	In Review.
2476-101461-121319	In Review.
2446-101412-041019 (2)	In Review.

2. Approved Amendments

2393-101263-102717 (3)	Approved by Designated Review.
2393-101263-102717 (2)	Approved by Designated Review.

3. Other

None.

C. New Veterinary Verifications/Consults 2500-101498-071720 In Review.

D. New Designated Member Determinations & Reviews

1. Pending	
2424-101227-082218 (1)	Withdrawn by the PI.
2393-101263-102717 (4)	In Review.

2. Assigned

101228	In Review.
101524	In Review.
2458-101418-061219	In Review.
101549	In Review.

E. Full Committee Reviews

101528	The proposal was withdrawn by the PI.
101531	The committee voted 9-0 to require modifications to secure approval.
	The modifications requested are attached.
2430-101373-091818	The committee voted 9-0 to require modifications to secure approval.
	The modifications requested are attached.
101486	The committee voted 9-0 to require modifications to secure approval.
	The modifications requested are attached.
101548	The committee voted 9-0 to require modifications to secure approval.
	The modifications requested are attached.
101550	The committee voted 9-0 to require modifications to secure approval.
	The modifications requested are attached.

F. Compliance Activities

- 1. Follow-up. None.
- 2. New. None.

VII. OTHER BUSINESS

A. Furlough issues and protocol review. Because there will be no veterinary review of protocols possible during the month of December, the IACUC voted 9-0 to cancel the December 2020 meeting. This situation affects all protocol submissions. Users will be informed regarding the change as well as a deadline for review of submissions.

VIII. NEXT MEETING

The next IACUC meeting is scheduled for September 3, 2020 at 3:00 pm via teleconference. The meeting deadline is August 26, 2020.

IX. ADJOURN

The meeting was adjourned at 3:50pm.

Protocol Review Comments Reference Number 101531 Review Summary

Section: Project Information Question: Extramural Funding Comments: Please add the information for account #180600-F1000-1000961

Section: Study Objectives

Question: Lay Summary

Comments: The lay summary is disorganized and must be rewritten. There is technical language that should be explained (ex. epigenetic, nociceptive) and the summary must be checked for spelling errors. Please use language understandable to a lay person with ahigh school understanding.

Section: Animals and Procedures

Question: Description of Experimental Design

Comments: 1. There remains a significant amount of redundant and/or unnecessary information. Word limit is currently over twice the maximum. Revise for brevity and clarity.

2. Various contradictory weight loss limits are described throughout the document. Please revise all sections for congruency.

3 Please provide more description for experiments A1-A4 and B2B6.

4. For B6, what does "leak in various organs" mean? Please clarify.

5. For E, the parental generation will be receiving IP injections and will be in category C. The following generations can be category B if nothing is done other than breeding. Please adjust the spreadsheet here and elsewhere.

Question: Procedure Description

Comments: Fecal transplants do not appear to be part of the Experimental Design. Please clarify.

Question: Procedure Description

Comments: This model is not described in the Experimental Design section. Please revise the entire document for congruency.

Question: Surgical Preparation

Comments: Pre-op scrubs should be performed three times.

Question: Surgical Preparation

Comments: 20% weight loss is inconsistent with what is stated elsewhere. Revise the entire document for clarity and congruency.

Section: Tumors, Cells, Antibodies, and Biologics

Question: Will tumors, cells or biologics of any kind be administered to animals as part of this proposal?

Comments: Endometrial cells from donor mice will be injected in D. They should be included here.

Protocol Review Comments Summary Report Reference Number 101373 Review Summary

Section: Administrative

Question: Protocol Associates

Comments: 1. For [Associate], please include the associate's years of experience with the species and responsibilities listed. If the associate does not have previous experience, please include who will train the associate and when that training is expected to be completed. This associate is also described as performing surgeries but is not listed in surgical personnel. Please clarify.

2. For [Associate], please include the associate's years of experience with the species and responsibilities listed. Please include when the associate was trained by the listed personnel.

3. For [Associate], please include the associate's years of experience with the species and responsibilities listed. Please include when the associate was trained by the listed personnel.

4. For [Associate], please include the associate's years of experience with the species and responsibilities listed. Please include when the associate was trained by the listed personnel.

5. For [Associate], this associate is described as performing surgery, but is not listed in surgical personnel. Please clarify.

Section: Study Objectives

Question: Lay Summary

- Comments: 1. The overall aim of this study is understandable to a layperson but some of the language used makes it unclear exactly what is being done by the study. It is clear that the aim of the study is important to human health but a bit confusing to a layperson exactly how this will be studied.
 - 2. Please define "anorectic."
- Section: Animals and Procedures

Question: Animal Number Justification

Comments: Specific Aim 6 describes new procedures on what appear to be a separate group of animals, yet no additional animals have been requested. Please clarify.

- Question: Description of Experimental Design
- Comments: 1. This section is over 3000 words long. Please note that a word limit will be required on the next annual review or continuation protocol.

2. The swim test should be included in the procedures section.

 Question:
 Location

 Comments:
 Is the forced swim test also conducted in one of these rooms?

 Question:
 Procedure Description

Comments: 1. Please describe the procedures in detail for each of the CUS stressors.

Specifically, describe the mechanism for tilting the cage; describe if the rats will be dried and returned to dry bedding cages following the wet bedding period; describe the mechanism for producing white noise; describe the caging for crowding.

2. Do the animals exposed to CUS stressors have free access to food and water? Do these stressors take place in the home cage? Please clarify.

3. How long will the NSC rats be handled each day?

4. Will the animals be observed for the entire swim test? What criteria would dictate an early end to the experiment?

Question: Duration and Frequency of the Procedure

Comments: 1. How long will each CUS animal be exposed each day?

2. How long will each control animal be handled each day?

Question: Prolonged Restraint Justification

Comments: Please describe the methods that will be used to assure the animals do not experience unnecessary pain or distress.

Question: Housing Description

Comments: The CUS rats are described as "crowded" housing with 4 rats to a cage for a period of time. Please include it here and provide an exemption justification below.

Protocol Review Comments Reference Number 101486 Review Summary

Section: Administrative

Question: Protocol Associates

Comments: [Associate A] is described as providing training to [Associate B]. Please add [Associate A] and complete the sections.

Section: Study Objectives

Question: Lay Summary

Comments: 1. The overall aim of this protocol is understandable but some of the technical wording used makes it unclear to a layperson. Please modify for a high-school level of understanding.

2. Please use lay language to explain/define mitochondria, ROS, ATP, synaptic plasticity, and symptomatology.

Section: Animals and Procedures

Question: Animal Number Justification

Comments: Please provide a chart outlining groups and numbers.

Question: Euthanasia Methods

Comments: Is this an appropriate means of euthanasia for rats that are not essential to the study, such as male breeders and culled littermates?

Question: Procedure Description

Comments: Will the animal be attended the entire time? What criteria would result in the experiment being stopped early?

Protocol Review Comments Reference Number 101548 Review Summary

Section: Administrative

Question: Protocol Associates

Comments: The associate, [Associate], needs to complete AALAS training as required by the IACUC policy. The appropriate modules were assigned on 8/3/2020.

Section: Study Objectives

Question: Lay Summary

Comments: 1. Some of the technical language would not be understandable to the average lay person; this section should be described in language understandable at a high-school level.
2. Define Fragile X

Section: Animals and Procedures

Question: Authorized Amounts

Comments: The summary table for total mice requested in the attachment of the animal number justification section has 144 mice in C and 4196 mice in D. Please clarify the difference.

Question: Animal Number Justification

Comments: 1. 720 mice are listed in category B, which is for breeding only. Category C should include any mice that require genotyping.

2. Please clarify which strains will be included in category B and which in category C.

- Question: Chemical Euthanasia Agents
- Comments: Please complete the sentence under 'dosage.'

Question: Surgical Preparation

Comments: The surgical site should be scrubbed three times with alternating betadine and alcohol.

Protocol Review Comments Reference Number 101550 Review Summary

Section: Questio Comm	on: ents:	Objectives Lay Summary The lay summary is too technical. Please rewrite the summary so it is tandable to a lay person with a high-school level of understanding.
Section: Question Comm	on: ents: 2. The overall 3. Are admini 4. Boo for adv should	Is and Procedures Description of Experimental Design 1. What age are the rats at the start of the study? time between mini-pump and catheter surgeries is mentioned, but the duration of the experiments on the animals is unclear. animals sacrificed immediately after the ~30 days of cocaine self- istration? A clearer timeline for procedures would be beneficial. dy weight loss and cataracts in older animals are monitored but monitoring verse effects of experimental agents administered is not mentioned, and be documented if expected. ght loss is usually capped at 15%.
Questi Comm		Chemical Euthanasia Agents Please remove sevoflurane as it is an anesthetic in this usage
Questi Comm		Procedure Description What is ITI?
	ents:	Procedure Description Will the animals be attended when they are outside of the animal facility hours? Room 319 does not have DLAR temperature and humidity pring.
Questi Comm		Procedure Description No procedure for intravenous injection is given. Please clarify.



Office of Research

Institutional Animal Care and Use Committee

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE September 3, 2020 Teleconference

The September 3, 2020 meeting of the University of South Carolina Institutional Animal Care and Use Committee (IACUC) was called to order by Shannon Davis, Chair, at 3:00 pm.

Committee Members Present:Dr. Shannon DavisIACUC ODr. Shayne BarlowAttendingCommittee Member IACommittee Member 98Committee Member 92Committee Member 125Committee Member 52Committee Member 91Committee Member 91Committee Member 77Alternate Member 01**early departure***non-voting

IACUC Chair Attending Veterinarian

I. APPROVAL OF MINUTES

A. The committee voted 10-0 to approve the August Minutes.

II. CHAIRMAN'S ANNOUNCEMENTS None.

III. ATTENDING VETERINARIAN'S ANNOUNCEMENTS None.

IV. IACUC ADMINISTRATOR'S ANNOUNCEMENTS

- **A.** Semi-annual Inspection and Program Review Report. The report will be presented for review no later than the October meeting. It will be uploaded for review and signature.
- B. PHS Assurance. OLAW review of the draft Assurance is on track.
- C. Assent Documents. New assent documents will be uploaded for review and signature.

D. NIH Request for Information Re: AAALAC Program Description and OLAW Assurance. The NIH has requested comments or information regarding proposed use of certain portions of AAALAC Program Descriptions in applicable section of the OLAW Assurance document. The deadline is November 28, 2020.

V. OLD BUSINESS

2476-101461-121319	Approved by Designated Review.
2434-101342-110518	Approved by Designated Review.
2471-101457-102119	Approved by Designated Review.
2430-101373-091818 (1)	Approved by Designated Review.
2467-101451-090319 (1)	Approved by Designated Review.
2464-101449-082819	Approved by Designated Review.
2463-101452-082619	Approved by Designated Review.
2403-101432-082019	In Review.
2462-101227-082218	
2461-101448-081419	Approved by Designated Review.
	Approved by Designated Review.
2422-101348-081318 (1)	Approved by Designated Review.
2500-101498-071720	Approved by Designated Review.
2458-101418-061219	Approved by Designated Review.
2492-101522-060320	Approved by Designated Review.
2414-101320-052218 (1)	Approved by Designated Review.
2446-101412-041019	Approved by Designated Review.
2407-101317-022118	Approved by Designated Review.
101228	Approved by Designated Review.
101407	Approved by Designated Review.
101486	Approved by Designated Review.
101491 (1)	Approved by Designated Review.
101494	In Review.
101524	Approved by Designated Review.
101527	In Review.
101531	In Review.
101532	Approved by Designated Review.
101534	Approved by Designated Review.
101537	Approved by Designated Review.
101538	Approved by Designated Review.
101539	Approved by Designated Review.
101542	Approved by Designated Review.
101548	In Review.
101549	In Review.
101550	In Review.

VI. NEW BUSINESS A. Annual Reviews

1. Renewals	
2423-101351-082218	In Review.
2426-101349-090518	Approved by Designated Review.
2428-101352-091718	Approved by Designated Review.
2429-101353-091718	Approved by Designated Review.
2430-101373-091818 (2)	Approved by Designated Review.
2432-101337-100818	In Review.
2433-101359-101018	Approved by Designated Review.
2459-101447-070819	In Review.
2468-101354-090319	In Review.
2469-101310-093019	In Review.
2473-101464-102319	Approved by Designated Review.
2474-101463-102819	Approved by Designated Review.
Admin VA-101383-	Submitted.
090718	

2. Terminations None.

B. New Administrative Action 1. Pending Amendments

1. i chuing i inchuinentis		
2467-101451-090319 (2)	In Review.	
2499-101533-070820	In Review.	

2. Approved Amendments

1203-101491-81120 (2)	Approved by Designated Review.
2354-101496-042720	Approved by Designated Review.
2355-101482-042720	Approved by Designated Review.
2413-101332-052218	Approved by Designated Review.
2478-101477-021920	Approved by Designated Review.
2479-101480-021920	Approved by Designated Review.
2480-101479-021920	Approved by Designated Review.
2493-101517-061620	Approved by Designated Review.
2500-101498-071720	Approved by Designated Review.

3. Other

None.

C. New Veterinary Verifications/Consults 2422-101348-081318 (2) In Review.

D. New Designated Member Determinations & Reviews

- 1. Pending None.
- 2. Assigned

2414-101320-052218 (2)	In Review.
2399-101260-111717	In Review.
101551	In Review.

E. Full Committee Reviews

2393-101263-102717	The committee voted 9-0-1 to require modifications to secure
	approval. The modifications requested are attached.
101553	The committee voted 10-0 to require modifications to secure
	approval. The modifications requested are attached.
101554	The committee voted 10-0 to require modifications to secure
	approval. The modifications requested are attached.
101555	The committee voted 10-0 to require modifications to secure
	approval. The modifications requested are attached.
101559	The committee voted 10-0 to require modifications to secure
	approval. The modifications requested are attached.
101560	The committee voted 10-0 to require modifications to secure
	approval. The modifications requested are attached.
101561	The committee voted 10-0 to require modifications to secure
	approval. The modifications requested are attached.
101562	The committee voted 10-0 to require modifications to secure
	approval. The modifications requested are attached.
101565	The committee voted 10-0 to require modifications to secure
	approval. The modifications requested are attached.

F. Compliance Activities

- 1. Follow-up. None.
- 2. New. PI # 122, ref#101227. Sick animals receiving a hazardous agent were not marked with the appropriate cage cards; this was an unintentional oversight resolved by the AV and the PI.

VII. OTHER BUSINESS

- A. Proposed changes to training policy. Deferred to October meeting.
- **B.** Benedict/UofSC collaboration. After discussion of this project, the IACUC voted 9-0 to require Benedict to submit a protocol for review by the UofSC IACUC. An MOU will also be put in place.

VIII. NEXT MEETING

The next IACUC meeting is scheduled for October 1, 2020 at 3:00 pm via teleconference. The meeting deadline is September 23, 2020.

IX. ADJOURN The meeting was adjourned at 4:00pm.

Protocol Review Comments Summary Report Reference Number 101263 Review Summary

Section: Study Objectives Question: Lay Summary Comments: The language used in this summary is understandable to a layperson and it shows the how the aim of the study is beneficial to human health. However, it does not provide information on how the study will be conducted nor what animals will be used and how they will be used.		
Section: Anim	als and Procedures	
Question:		
Comments:		
Question: Comments: frequency wi		
Section: Tumo	ors, Cells, Antibodies, and Biologics	
Question:	Exemption Explanation	
Comments:	Certification or retesting of the cell lines is required prior to approval.	
Section: Alter Question: Comments:	natives and Duplication Consideration of Alternatives Please update the search to include the new compounds and cell lines.	
Question: Comments:	Verification that Studies are not Duplicative Please update the search to include the new compounds, cell lines, etc.	

Protocol Review Comments Summary Report Reference Number 101553 Review Summary

Section: Administrative

Question: Protocol Associates

Comments: 1. [Associate] needs to complete online training AALAS Learning Library: Laboratory Animal Allergy, Working with the IACUC, and Working with the Laboratory Mouse; these were assigned 8/24/20.

2. [Associate] is listed as performing surgery but is not listed in surgical personnel. Please clarify.

Section: Study Objectives

Question: Lay Summary

Comments: 1. The language used in this summary is understandable to a layperson and it shows that the aim of the study is important to human health. However, it does not tell how the summary will be conducted or what animals will be used and how they will be used.

2. How will the role of macrophages on cancer cachexia be studied?

Section: Animals and Procedures

Question: Strains Not Listed

Comments: 1. The Jax strain can be selected from the database and deleted here. 2. Please provide more information for the Taconic strain. It is not listed in their catalogue.

Question: Animal Number Justification

Comments: 1. Please justify a group size of 6 for imaging purposes.

2. Define "Mfs;" all abbreviations should be defined on first use.

3. What are Kpp mice? Please use annotation consistent with other sections of the protocol.

Question: Description of Experimental Design

Comments: 1. Specific Aim 1 describes "hindlimb muscle irradiation." How will this be accomplished?

2. Endpoints should include reduced mobility and/or lameness.

3. Please limit weight loss to 15%.

4. ApcMin/+; Sucner1/Gpr91 mice are described. Are these mice being generated by breeding on this protocol or another protocol? They are not listed in the transfer section.

5. Scarb1 and Suncnr1/Gpr91 mice are not included in the mouse models section.

6. This section is over 4000 words; it exceeds the 1500-word limit. The detailed description of experiments can be removed because they are described in the Procedures section.

7. Aim 2 proposes new mouse models; please describe the expected phenotype.

8. What is a hyper-metabolic mouse?

proposed to accelerate cachexia, is it reasonable to conduct studies at 20 weeks?			
Question:	Euthanasia Methods		
Comments:	Isoflurane cannot be injected IP		
Question:	Procedures		
Comments:	Tissue collection after Euthanasia will be performed; please add it here.		
Question:	Location		
Comments:	Please delete SoM room A28 and select the CT room.		
Question:	Location		
Comments:	Will this be done in a procedure room, or an animal room?		
	Procedure Description 1. Please include a description of the collection of bone marrow from , which would require tissue collection after euthanasia. , ice are only used for bone marrow after euthanasia, they would be in		
Question: Comments: here.	Other Therapeutic Drugs The antibiotics should be moved from Experimental Agents and listed		
Question:	Location		
Comments:	Please select the correct room for imaging procedures.		
Question:	Survival Surgical Procedures		
Comments:	Please select "hydrodynamic limb injection."		
Question:	Surgical Personnel Experience		
Comments:	[Associate] is listed as performing surgery in Protocol Associates but is		
not listed here	e. Please clarify.		
Question:	Surgical Preparation		
Comments:	3 alternating scrubs of iodine and alcohol should be used.		
Question:	Postoperative or Preemptive Analgesics		
Comments:	Please indicate the frequency and duration, i.e., "once after surgery then		
every hour	rs for days, then as needed."		
Question:Postoperative Monitoring and CareComments:Explain the postoperative analgesic administration. Multiple drugs areproposed - when will each be used?			

9. If cachexia is evident in the Apc min model after 12 weeks, and these models are proposed to accelerate cachexia, is it reasonable to conduct studies at 26 weeks?

Question:	Restraint	
Comments:	Please complete the section.	
Question:	Hazardous Agents	

If tamoxifen is given by IP, then please include it in that section. Comments:

Tumors, Cells, Antibodies, and Biologics Section:

> Question: Source of Material

1. Is the cell line C-26 or MC38? Please review all sections for Comments: congruency and make the necessary corrections.

2. Rodent cell lines must be tested prior to approval of this AUP. Please submit the most recent testing certificate.

Alternatives and Duplication Section:

Consideration of Alternatives Question:

Comments: Please perform a literature search for alternatives to animal use and indicate the databases searched, the date of the search, period covered, and keywords used. This information belongs in Rationale for Animal Use.

Protocol Review Comments Summary Report Reference Number 101554 Review Summary

Section: Administrative

Question: Protocol Associates

Comments: 1. [Associates] is listed in surgical personnel, however the responsibilities listed do not include surgical procedures. Please clarify.

2. In [Associate] "Comments" section, it describes training [former associate] who is not listed as an associate on this protocol. Please clarify.

3. [Associate] has the AALAS Modules, Refresher: Working with the IACUC and Working with the Laboratory Mouse, assigned 7/1/2020, to complete.

Section: Study Objectives

Question: Lay Summary

Comments: The language used and benefit to human health in this summary are understandable to a layperson. However, some of the technical terms create a lack of overall clarity.

Section: Animals and Procedures

Question: Animal Number Justification

Comments: 1. Please clarify your category assignments. Category B is for mice that are bred, but not genotyped. You are proposing genotyping by tail snip, which would place those mice in Category C.

2. Please justify a group size of 5 for experiments in 2.

Question: Breeding Justification

Comments: Please be consistent with labelling experiments. In the first section, "project 2" is labeled as "1A" in the animal number justification section.

Question: Description of Experimental Design

Comments: 1. Please limit weight loss to 15% instead of 20%.

2. Please be consistent in the exclusion criteria. Some sections say mice will be removed from the study after a 10% body weight loss. Is this correct?

Question: Euthanasia Methods

Comments: Based on the procedures described, the method of euthanasia seems to be cervical dislocation under anesthesia, not anesthetic overdose. Anesthetic overdose can be removed.

Question: Procedure Description

Comments: The procedure description for subcutaneous injection is same as that for survival surgery below; please clarify.

Question: Surgical Personnel Experience

Comments: In Protocol Associates, surgery is not listed for [Associate]. If [Associate] will be performing surgery, please add "surgery" to his responsibilities in Protocol Associates; If he is not performing surgery, please remove him from this section.

Section: Alternatives and Duplication Question: Rationale for Animal Use Comments: What is the rationale for miR489?

Protocol Review Comments Summary Report Reference Number 101555 Review Summary

Section: Administrative

Question: Protocol Associates

Comments: 1. [Associate] needs to complete the AALAS module, Working with the Laboratory Rat. The module was assigned 8/27/20.

2. There are additional procedures listed on this protocol that are not accounted for within the listed associates' "responsibilities." Please include all procedures to be performed in the "Responsibilities" section of the associate(s) who will perform them, and describe the individual's experience with those procedures in the "Comments" section. (IP injection, Admin of Special Diet, BP Measurement, Non-Survival Sx).

Section: Study Objectives

Question: Lay Summary

Comments: The language used is understandable to a layperson and the summary defines how the aim of the study is important to human health.

Section: Animals and Procedures

Question:Animal Number JustificationComments:Please explain why two rat stocks are being used.

Question: Description of Experimental Design

Comments: 1. It appears that some animals will receive daily IP injections for up to 10 consecutive weeks (70 IP injections). Please indicate why osmotic pumps or programmable, refillable infusion pumps are not used to replace repeated IP injections.

2. Rats in Aim 1 appear to be a combination of DSI implanted rats (singly housed) and non-surgerized (group housed). Please note that there are robust documented effects of housing conditions on resting blood pressure. Consider singly housing all rats that need to be compared with the DSI implanted rats.

Please consider the use of a cellulose patch at the insertion site to be placed on the catheter/descending aorta, and then vetbond placed on top of that for a stronger seal.
 Please condense this section by moving surgical descriptions to the appropriate Surgery sections.

Question:	Location
Comments:	Will the animals receiving daily injections be moved to the lab daily?
Why?	

Question:Procedure DescriptionComments:Please include the needle size and maximal volume.

Question: Location

Comments: The room indicated is a mouse room. Please select "SoM Animal Room" and contact the DLAR supervisor for more information when administration of the diet is being planned.

Question: Procedure Description

Comments: Please indicate how the animals will be transported to and from the lab as well as how long they will be there in total.

Question:Survival Surgical ProceduresComments:Please select the surgical procedure.

Question: Surgical Procedure

Comments: Consider the use of a cellulose patch at the insertion site to be placed on the catheter/descending aorta, and then vetbond placed on top of that for a stronger seal.

Question: Instrument Sterilization

Comments: How many times will instruments be flash sterilized using a bead apparatus before they are reautoclaved? At minimum, instruments should be reautoclaved every 5 surgeries.

Question:Postoperative or Preemptive AnalgesicsComments:Please change frequency to "24h and 48h post surgery, then as needed" for
maximum flexibility.

Question:Postoperative Monitoring and CareComments:Please clarify "the animals will be moved to a warm, dry area..." byincluding the source of heat.

Question:RestraintComments:It appears animals will be restrained for 10 minutes for blood pressuremeasurements.Please select "yes" and complete the section.

Section: Alternatives and Duplication Question: Rationale for Animal Use Comments: Please include a rationale for each rat stock.

Section: Principal Investigator's Assurance

Question:Principal Investigator's Assurance StatementComments:The assurance and proposal must be signed and submitted by the PI onresubmission

Protocol Review Comments Summary Report Reference Number 101559 Review Summary

Section	on: Anima	and Procedures
	Question:	Description of Experimental Design
	Comments:	Please limit weight loss to 15%.
	Question:	Euthanasia Methods
Comments: Is anesthetic overdose correct? There are two different descriptions. C appears to be decapitation under anesthesia, and one appears to be exsanguination under anesthesia (a non-survival surgery).		
	Question:	Procedure Description
	Comments: sites.	Please list the maximal injection volume (2.5 mL?) and alternate injection
	Question: Comments:	Procedure Description Please limit weight loss to 15%.

Protocol Review Comments Summary Report Reference Number 101560 Review Summary

Section: Study Objectives

Question: Lay Summary

Comments: 1. This summary uses language that is understandable to a layperson and also defines how the aim of the study is important to human health.

2. Reference to a prior approval period makes this sound like a continuation. Is it? Please clarify.

Section: Animals and Procedures

Question: Animal Number Justification

Comments: 1. Why is there a "male animals justification" section? Both sexes are being used.

2. Section A indicates that they are now requesting an additional 160 animals, but section B indicates 240 animals. The approved animal numbers are 240. Please clarify

Question: Duration and Frequency of the Procedure

Comments: Please elaborate on the Y maze. It is tested once for a max of 2 min/trial, but it appears as though there are multiple trials. Please clarify.

Question: Surgical Preparation

Comments: Please respond to the section instructions. The surgical site must be clipped and cleaned prior to surgery, and the surgeon must wear gloves.

Protocol Review Comments Summary Report Reference Number 101561 Review Summary

Section: Administrative

Question:Protocol AssociatesComments:1. [Associate] is described as providing training for the associate[Associate] but is not listed as an associate on this protocol. Please clarify.2. For [Associate], please include when training is expected to be complete in the"comments" section.

Question:ContinuationComments:The Lay Summary references "the prior approval period." If this is acontinuation of a current or recently expired study, select "yes" and fill out the section.

Section: Study Objectives

Question: Lay Summary

Comments: 1. The language used and benefit to human health in this summary are understandable to a layperson. However, there is no explanation of how the study will be conducted or what animals will be used and how they will be used.

2. The discussion of the protective effects of estrogen distracts from the study design to look at drug interactions.

Section: Animals and Procedures

Question:Animal Number JustificationComments:A separate justification for using male animals is not necessary, as bothsexes are being used.

Question:Description of Experimental DesignComments:Please confirm that the IACUC Policy on Endpoints for this model will befollowed.

Question:Duration and Frequency of the ProcedureComments:Please alternate the IP injection sites

Question:Surgical PreparationComments:At a minimum, the surgical site must be clipped and cleaned, and thesurgeon must wear gloves.

Question:Non-Survival Surgery EuthanasiaComments:Please include tissue collection after euthanasia in the Procedures section.

Protocol Review Comments Summary Report Reference Number 101562 Review Summary

Question: Comments: understandable	Objectives Lay Summary The language used and benefit to human health in this summary are to a layperson. However, there is no explanation of how the study will be what animals will be used and how they will be used.
Question: Comments:	als and Procedures Animal Number Justification Please revise the sentence "We request an additional 80 animals" The sould be included in the total requested.
Question: Comments: this model.	Description of Experimental Design Please confirm that the IACUC policy on endpoints will be followed for
Question: Comments: procedure.	Procedure Description IP injections are described here. Please include them as a separate
Question: Comments: How will they	Duration and Frequency of the Procedure What is the maximum time that animals will be removed from DLAR? be monitored during this time?
Question: Comments: Euthanasia in	Non-Survival Surgical Procedure If tissue are being collected, please also include Tissue Collection after the Procedures.
Question: Comments: the surgeon m	Surgical Preparation At a minimum, hair must be clipped, the surgical site must be cleaned, and nust wear gloves.

Question:Surgical PreparationComments:What will be done to ensure adequate anesthetic depth, that the animal isnot conscious?

Protocol Review Comments Summary Report Reference Number 101565 Review Summary

Question: Comments:	Objectives Lay Summary The language used is understandable to a layperson, but the objective or e study is unclear.
Section: Anima	als and Procedures
Question:	Authorized Amounts
Comments:	Animals undergoing anesthesia for tail fin biopsy will be Category D.
Comments:	Breeding Numbers Please check the numbers to ensure consistency with other parts of the total number of offspring weaned in this table exceeds the total number of
Question: Comments:	Procedure Description Please move the fin biopsies to the Surgery section.



Office of Research

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

October 1, 2020 Teleconference titutional Animal Care and Use Committee

The October 1, 2020 meeting of the University of South Carolina Institutional Animal Care and Use Committee (IACUC) was called to order by Shannon Davis, Chair, at 3:01 pm.

Committee Members Present:Dr. Shannon DavisIACUC ChairDr. Shayne BarlowAttending VeterinarianCommittee Member IACommittee Member 86Committee Member 125Committee Member 147Committee Member 52*Committee Member 128*late arrival **early departure***non-voting

I. APPROVAL OF MINUTES

The committee voted 8-0 to approve the September Minutes.

II. CHAIRMAN'S ANNOUNCEMENTS None.

III. ATTENDING VETERINARIAN'S ANNOUNCEMENTS

The USDA conducted its annual (focused) inspection on September 9, 2020. There were no citations.

IV. IACUC ADMINISTRATOR'S ANNOUNCEMENTS

- a. Assent documents. Assent documents have been distributed for signatures.
- b. Semi-annual Inspection and Program Review Report. The semi-annual report has been distributed for signatures.
- c. PHS Assurance. The Assurance is under review by OLAW.
- d. Proposed USDA rule changes to research facility regulations. The proposed change to the AWA that would have the most impact on IACUC workload is removal of the annual review requirement.
- e. Holiday-related schedules/deadlines. Revised target dates and deadlines for both IACUC and DLAR were discussed and will be sent to all animal users in mid-

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October.

V. OLD BUSINESS

,	
2399-101260-111717	Approved by Designated Review.
2393-101263-102717	Approved by Designed Review.
2432-101337-100818	In Review.
2469-101310-093019	In Review.
2467-101451-090319	Approved by Designated Review.
2468-101354-090319	Approved by Designated Review.
2423-101351-082218	Approved by Designated Review.
2424-101227-082218	Approved by Designated Review.
2422-101348-081318	Approved by Designated Review.
2499-101533-070820	Approved by Designated Review.
2459-101447-070819	Approved by Designated Review.
2414-101320-052218 (1)	Approved by Designated Review.
101494	Withdrawn at Request of PI.
101527	Approved by Designated Review.
101531 (1)	Approved by Designated Review.
101548 (1)	Approved by Designated Review.
101549	Approved by Designated Review.
101550	Approved by Designated Review.
101551	Approved by Designated Review.
101553	In Review.
101554	In Review.
101555	In Review.
101559	Approved by Designated Review.
101560	In Review.
101561	Approved by Designated Review.
101562	In Review.
101565	Approved by Designated Review.

VI. NEW BUSINESS

A. Annual Reviews

1. Renewals

2471-101457-102119	In Review.
2431-101368-100218	In Review.
2472-101462-102119	In Review.
2434-101342-110518	Approval Pending.
2437-101355-121318	Approval Pending.
2476-101461-121319	In Review.

2. Terminations None.

B. New Administrative Action

I. Pending Amendments		
2409-101321-031918	In Review.	
2510-101486-083120 (2)	In Review.	
2452-101425-050119	In Review.	
2450-101426-042219	In Review.	
2496-101484-062420	In Review.	

2. Approved Amendments

2419-101345-072318	Approved by Designated Review.
2414-101320-052218 (2)	Approved by Designated Review.
2510-101486-083120 (1)	Approved by Designated Review.
2514-101531-091520 (2)	Approved by Designated Review.
2508-101542-082120	Approved by Designated Review.
2455-101389-050819	Approved by Designated Review.

3. Other

None.

C. New Veterinary Verifications/Consults

2478-101477-021920	Approved by Designated Review.
2444-101422-040519	Approved by Designate Review.
2500-101498-071720	Approved by Designated Review.

D. New Designated Member Determinations & Reviews

1. Pending	
2482-101472-030220	In Review.
101573	In Review.

2. Assigned

2513-101548-090920 (2)	In Review.
2425-101350-082718	Approved by Designated Review.
2492-101522-060320	In Review.
101557	In Review.
101570	In Review.

E. Full Committee Reviews

101558	The committee voted 9-0 to require modifications to secure
	approval. The modifications requested are attached.
101567	The committee voted 9-0 to require modifications to secure
	approval. The modifications requested are attached.
101566	The committee voted 9-0 to require modifications to secure
	approval. The modifications requested are attached.
101569	The committee voted 9-0 to require modifications to secure
	approval. The modifications requested are attached.

101572The committee voted 9-0 to require modifications to secure
approval. The modifications requested are attached.

F. Compliance Activities

- 1. Follow-up. None.
- 2. New. None.

VII. OTHER BUSINESS

A. The committee voted 9-0 to approve the proposed changes to the training policy.

VIII. NEXT MEETING

The next IACUC meeting is scheduled for November 5, 2020 at 3:00 pm via teleconference. The meeting deadline is October 28, 2020.

IX. ADJOURN The meeting was adjourned at 4:00pm.

Protocol Review Comments Summary Report Reference Number 101558 Review Summary

Section: Administrative

Question: Protocol Associates

Comments: [PI] has an AALAS module, Pain Management in Laboratory Animals, assigned 9/24/20, to complete.

Section: Study Objectives Question: Lay Summary Comments: Please provide brief information on the proposed compound and why is being studied.

Section: Animals and Procedures

Question:Animal Number JustificationComments:Per the instructions, please justify the group size of 5.

Question: Description of Experimental Design

Comments: 1. Please list the compounds and doses that will be administered using the nerve cuff.

2. Please discuss the expected clinical outcomes of the nerve crush and describe clinical endpoints that will be used to determine if an animal should be removed from the study.

Question:Surgical PreparationComments:Please clarify that three cycles of betadine/ethanol will be conducted.

Section: Alternatives and Duplication

Question: Rationale for Animal Use

Comments: Please clarify 'drug-impregnated Poly'. Is this what the cuff is composed of? It is not specified elsewhere.

Question:Consideration of AlternativesComments:Please correct the date of the literature search.

Protocol Review Comments Summary Report Reference Number 101567 Review Summary

Section: Administrative

Question: Protocol Associates

Comments: 1. "Assist Investigators" suggests the PI and/or additional personnel will be working with the animals. Please add all personnel that will be working with the animals in this protocol.

2. Visiting personnel need to be listed here. They will need to complete USC's online training, or document equivalent training from their institution and be approved before performing any live animal work. For the OHSP, the

Section: Animals and Procedures

Question: Procedure Description

Comments: Please move rotorod from grip strength testing to the appropriate procedure section

Question:Procedure DescriptionComments:Please specify what tissues will be collected.

Question: Procedure Description

Comments: 1. Is the Y maze cleaned after each use? Please clarify.

2. Please refer to "behavioral traits" instead of "personality" of the mouse--"behavioral traits" may be more in line with the measurement.

Question: Duration and Frequency of the Procedure

Comments: The estrus cycle of a mouse is 4-5 days. Of what value will data be from measuring the estrus cycle once per week, and how will these measurements be compared between groups?

Question: Restraint

Comments: The escape test is considered a restraint procedure and should be included here.

Protocol Review Comments Summary Report Reference Number 101566 Review Summary

Section: Administrative

Question: Protocol Associates

Comments: In Comments, please provide [PI's] training and experience with the species and procedures listed in his Responsibilities section.

Section: Study Objectives

Question: Lay Summary

Comments: 1. The summary uses language understandable to a layperson the aim of the study is shown to be beneficial to human health.

2. Please specify the animal model being used.

Section: Animals and Procedures

Question:Category E JustificationComments:These should be mice, not rats.

Question: Animal Number Justification

Comments: 1. Please reduce the length of this section, using 1500 words as a guide. 2. Per the instructions, please justify group sizes and total number of animals used. A spreadsheet that details groups and treatments may be attached.

3. The rationale for each experiment and procedures can be presented in the Description of Experimental Design section.

4. What are CNO and C21?

5. Procedures should be described in the Procedures section. In this section, list the experimental groups, number of animals per group, and their treatments.

Question: Description of Experimental Design

Comments: Please rephrase the section entitled "Endpoints." This phrase is used to reference when mice are removed from the protocol and euthanized.

Question: Procedures

Comments: Please add tissue collection after euthanasia.

Question: Procedure Description

Comments: 1. Please use the suggested procedure as a guide and modify it to your specific experiment.

2. Please describe how the IP procedure will be performed.

3. Please indicate that aspiration will be performed to ensure that the urinary bladder or intestines have not been punctured prior to injection.

Question: Procedure Description

Comments: If this information is described in the Surgery section, it can be deleted here.

Question: Multiple Survival Surgery Plans

Comments: The justification is duplicated in this section. Please remove the last two sentences that are also identically addressed in the justification section below.

Question: Surgical Preparation

Comments: The surgeon should also wear a mask. Will surgical personnel wear surgical scrubs, lab coat, or a gown? Please clarify.

Question:Surgical PreparationComments:Microwaveable heat pads can become quite hot; how will burns beprevented?

Question:Surgical PreparationComments:Please describe how the animal is prevented from coming into contactwith the liquid isoflurane in the bell jar. Is there a barrier present?

Section: Pharmaceutical Grade Compounds

Question:Non-Pharmaceutical Grade CompoundsComments:In the Justification column, please indicate why non-pharmaceuticalinstead of pharmaceutical grade compounds are used - not why they are used.

Section: Alternatives and Duplication

Question: Rationale for Animal Use

Comments: Per the instructions, please include a justification for the use of each mouse strain used; it can be transferred from the Animal Number Justification section.

Protocol Review Comments Summary Report Reference Number 101569 Review Summary

Section: Administrative

Question: Protocol Associates

Comments: 1. Please add all personnel who will handle live animals or perform the procedures listed in this protocol, including the PI if he will do live animal work, and complete the sections. If the associates are not listed within Topaz, please contact [IACUC Office] at 5768417 to have them added.

2. [PI] is listed in surgical personnel. Please add him here and complete the section

Section: Animals and Procedures

Question: Animal Number Justification

Comments: 1. More explanation of the model is necessary. It isn't clear from the first sentence that 4T1 cells are tissue culture cells that will be injected into mice to generate breast cancers.

- 2. What are MDSCs? Abbreviations should be defined on first use.
- 3. Per the instructions, please explain/justify group sizes of 10, and 20.
- 4. Please explain alternate names for mice. Are S100a4-cre mice Fsp1-cre mice?
- 5. Please explain adaptive transfer what is being injected into the tail vein?

Question: Phenotype Management

Comments: Please remove this statement. This section concerns care needed for phenotypes specific to the strains being used.

Question: Mating System Description

Comments: 1. Please provide more description of the planned matings.

2. Are Fsp1-cre mice hemizygous? Is the goal to produce Fsp1-cre; Klf4flox/+, or do you need an additional cross to generate Fsp1-cre; Klf4flox/flox?

3. When are the GFP+ mice being used? These crosses aren't reflected in the table below, please revise/correct the table.

4. 10 litters are described in the animal number justification. Are ten litters necessary for all crosses? Please clarify.

5. After female mice are 6 months old, not many litters can be expected. Consider switching your breeding to replace breeders every 6 months.

6. Will breeding be stopped after 10 litters, or will you continue breeding for the 3 year AUP to maintain the lines?

7. How many generations are you backcrossing Klf4 mice to BalB/C before you use them in other crosses?

8. The SOM is quite full; how many cages will be required at one time?

Question: Description of Experimental Design

Comments: 1. Please provide a rationale for the proposed experiments. Specific details can be explained below in the procedures section.

2. Please clarify if ear or tail tissue will be used for genotyping.

3. Why are you obtaining bone marrow and dorsal skin?

4. Surgical preparation should include three alternating scrubs of alcohol then betadine or chlorhexidine.

Questi Comm		uthanasia Methods ease add C02 asphyxiation.
Questi Comm		nemical Euthanasia Agents ease remove isoflurane, as it is not being used for euthanasia.
	nents: Pl	ocedures ease add tissue collection after euthanasia and any other procedures, ssociated with adoptive transfer.
Comm	nents: [P	argical Personnel Experience [1] has not completed the AALAS surgical modules. The appropriate signed 9/24/20.
Comm admin	nents: A	ostoperative or Preemptive Analgesics t a minimum, a single dose of carprofen or equivalent should be er tumor removal. This surgery will involve tissue trauma and post- fort is expected.
Questi Comm		ssessing Postoperative Pain, Distress and/or Discomfort omplete the section.
Section: Questi	•	Cells, Antibodies, and Biologics as the material(s) been tested for rodent viruses?

Question: Has the material(s) been tested for rodent viruses? Comments: This test is 7 years old; please have the cells retested, certify that the cells have been held in storage, or use another source with recent testing.

Section: Alternatives and Duplication

Question:Consideration of AlternativesComments:An alternatives search is required. Please perform a search for alternatives.AWA and the search for alternatives.

Protocol Review Comments Summary Report Reference Number 101572 Review Summary

Section: Administrative

Question: Protocol Associates

Comments: The information for most associates appears outdated. Please update the amount of experience personnel have with the species and/or procedures. Also, please omit dates of AALAS training; a statement of "Has completed all required AALAS training" is sufficient and does not require frequent updating.

1. The associate, [associate], has not completed the AALAS module, Working with the Laboratory Mouse. The module was assigned 9/25/20.

2. The associate, [associate], has 5 AALAS modules, assigned 8/3/20, to complete. This associate's animal facility access was revoked 9/21/20. Please give more information in the "comments" section regarding the amount of experience and/or training this associate has (ie, how long, where, and by whom). [Associate] will be inactivated until required online training is complete.

3. For [associate], please give more information in the "comments" section regarding the amount of experience and/or training this associate has (ie, how long, where, and by whom).

4. For [associate], please give more information in the "comments" section regarding the amount of experience and/or training this associate has (ie, how long, where, and by whom). Please include when training for this associate is expected to be complete. [associate] is described as providing training but is not listed on this protocol. Please Clarify.

5. For [associate], please give more information in the "comments" section regarding the amount of experience and/or training this associate has (ie, how long, where, and by whom). Please include when training for this associate is expected to be complete.
6. For [associate], please give more information in the "comments" section regarding the amount of experience and/or training this associate has (ie, how long, where, and by

whom). Please include when training for this associate is expected to be complete.

7. For [associate], please give more information in the "comments" section regarding the amount of experience and/or training this associate has (ie, how long, where, and by whom). Please include when training for this associate is expected to be complete. [Associate] is described as providing training but is not listed on this protocol. Please Clarify.

8. For [associate], please give more information in the "comments" section regarding the amount of experience and/or training this associate has (ie, how long, where, and by whom). Please be more specific in the "responsibilities" section. As written, it sounds as if they may participate in some or all aspects of the study, including surgery, but they are not listed in surgical personnel. Please clarify.

9. For [associate], please give more information in the "comments" section regarding the amount of experience and/or training this associate has (ie, how long, where, and by whom).

10. For [associate], please give more information in the "comments" section regarding the amount of experience and/or training this associate has (ie, how long, where, and by whom). Please include when training for this associate is expected to be complete. 11. For [associate], Please give more information in the "comments" section regarding the amount of experience and/or training this associate has (ie, how long, where, and by whom. Please include when training for this associate is expected to be complete. 12. For [associate], please include when training for this associate is expected to be complete.

13. For [associate], please include when training for this associate is expected to be complete.

14. For [associate], please include when training for this associate is expected to be complete.

15. For [associate], please be more specific in the "responsibilities" section. As written, it sounds as if they may participate in some or all aspects of the study, including surgery, but they are not listed in surgical personnel. Please clarify.

Section: Animals and Procedures

Ouestion: Animal Number Justification

Comments: 1. Per the instructions, this section should include information on group sizes, animal numbers classified by USDA pain category, and power analysis.

2. The group sizes are justified appropriately in experiment 1, but it isn't continued for the following experiments. Add justifications for the numbers.

Question: Transfer Information

Comments: The protocol 2369-101242-072617 has expired. Please select an active AUP.

Question: Description of Experimental Design

Comments: 1. Please add drinking water administration to list for CDKI.
2. A list of experiments and their procedures would be helpful. Experiment descriptions can be attached, and procedures described in the appropriate Procedures section.
3. Weight loss is generally capped at 15%. Please justify why 20% would be necessary.

Question: Euthanasia Methods

Comments: Secondary forms of euthanasia for the primary methods are mentioned elsewhere; please add them here.

Question:	Chemical Euthanasia Agents
Comments:	Isoflurane is not being used for euthanasia and should be removed.

- Question: Procedure Description
- Comments: Please alternate the injection site.
- Question:Experimental Agent TableComments:Please remove minipump delivery; this section covers IP injections.

Question:Procedure DescriptionComments:Remove repeated sentence.

Question: Location Comments: Euthanasia cannot be conducted in an animal housing room. Please select another location

Question: Survival Surgery Location

Comments: Surgery cannot be performed in an animal housing room. Please select a procedure room.

Question: Surgical Personnel Experience

Comments: 1. The sections appear outdated. Please update the amount of experience personnel have with the species and/or procedures. Also, omit dates of AALAS training; a statement of "Has completed all required AALAS training" is sufficient and does not require frequent updating.

2. Please give a timeframe for training to be completed for [6 associates].

Question:Surgical PreparationComments:The surgical site must be cleaned and shaved. The surgeon must weargloves.Surgical site must be cleaned and shaved. The surgeon must wear

Question: Surgical Procedure

Comments: How are the animals prevented from coming into contact with liquid isoflurane in the bell jar?



INSTITUTIONAL ANIMAL CARE AND USE COMMITTE Etitutional Animal Care and Use Committee Videoconference

The November 5, 2020 meeting of the University of South Carolina Institutional Animal Care and Use Committee (IACUC) was called to order by Shannon Davis, Chair, at 3:00 pm.

Committee Members Present:Dr. Shannon DavisIACUC ChairDr. Shayne BarlowAttending VeterinarianCommittee Member IACommittee Member 86Committee Member 147Committee Member 128Committee Member 121*Committee Member 121*Committee Member 123Committee Member 01*late arrival**early departure***non-voting

I. APPROVAL OF MINUTES

The committee voted 8-0 to approve the October 2020 Minutes.

II. CHAIRMAN'S ANNOUNCEMENTS None.

III. ATTENDING VETERINARIAN'S ANNOUNCEMENTS

The AV discussed information from the recent AALAS conference:

- 1. There are proposals and discussions underway to make the *Guide* a living document, which means it could be updated at any time, requiring immediate enforcement with changes that could negatively impact an institution's ability to comply for financial or other reasons.
- 2. Studies are showing that human pathogens and other unforeseen issues are rapidly increasing in colonies of humanized mice. Because of this, the AV is working closely with UoSC's Biosafety Officer to revise the IACUC's policy on cell line testing. It will be submitted for review as soon as possible.

IV. IACUC ADMINISTRATOR'S ANNOUNCEMENTS

1. Assent documents. Due to changes to the review policy (see Other Business), the

Assent documents will be updated and circulated for signature.

- 2. PHS Assurance. The Assurance was returned to OLAW October 26th and is under review.
- Holiday-related schedules/deadlines. Revised target dates and deadlines for both IACUC and DLAR were discussed and sent to all animal users in mid-October.
 a. The last date for orders delivered the week after Thanksgiving is November 19th.
 b. The last date for orders delivered the first week of January 2021 is December 17th.

V. OLD BUSINESS

V. ULD DUSINESS	
2476-101461-121319(1)	Approved by Designated Review.
2472-101462-102119	Approved by Designated Review.
2471-101457-102119	Approved by Designated Review.
2432-101337-100818	In Review.
2431-101368-100218	Approved by Designated Review.
2469-101310-093019	Approved by Designated Review.
2513-101548-090920	Approved by Designated Review.
2510-101486-083120	Approved by Designated Review.
2496-101484-062420	Approved by Designated Review.
2492-101522-060320(1)	Approved by Designated Review.
2452-101425-050119	Approved by Designated Review.
2450-101426-042219	Approved by Designated Review.
2409-101321-031918	Approved by Designated Review.
2482-101472-030220	Approved by Designated Review.
101553	In Review.
101554	Approved by Designated Review.
101555	In Review.
101557	Approved by Designated Review.
101558	Approved by Designated Review.
101560	Approved by Designated Review.
101562	Approved by Designated Review.
101566	Approved by Designated Review.
101567	In Review.
101569	In Review.
101570	Approved by Designated Review.
101572	Approved by Designated Review.
101573	Approved by Designated Review.

VI. NEW BUSINESS

A. Annual Reviews

Approved.
Approved.
Approved.
Approved.

2. Terminations None.

B. New Administrative Action 1. Pending Amendments

2428-101352-091718	In Review.
2453-101406-050119	In Review.

2. Approved Amendments

2411-101314-032318	Approved by Designated Review.
2419-101345-072318	Approved by Designated Review.
2424-101227-082218	Approved by Designated Review.
2425-101350-082718	Approved by Designated Review.
2426-101349-090518	Approved by Designated Review.
2430-101373-091818	Approved by Designated Review.
2467-101451-090319	Approved by Designated Review.
2476-101461-121319 (2)	Approved by Designated Review.
2483-101471-030420	Approved by Designated Review.
2488-101501-051220 (1)	Approved by Designated Review.
2488-101501-051220 (2)	Approved by Designated Review.
2499-101533-070820	Approved by Designated Review.
2433-101359-101018	Approved by Designated Review.

3. Other

Admin VA-101582-091020 VA project with USC admin file only.

C. New Veterinary Verifications/Consults

2509-101228-082620	Approved by Designated Review.
2478-101477-021920	Approved by Designated Review.
2451-101423-042519	Approved by Designated Review.

D. New Designated Member Determinations & Reviews

1. Pending None.

2. Assigned	
2519-101561-092820	In Review.
2492-101522-060320 (2)	In Review.
2489-101521-051920	In Review.
2474-101463-102819	In Review.
2434-101342-110518	In Review.
101577	Approved by Designated Review.

101576 In Review.

E. Full Committee Reviews

2468-101354-090319	The committee voted 9-0 to require modifications to secure approval. The modifications requested are attached.
2437-101355-121318	The committee voted 9-0 to require modifications to secure approval. The modifications requested are attached.
101586	The committee voted 9-0 to require modifications to secure approval. The modifications requested are attached.
101583	The committee voted 9-0 to require modifications to secure approval. The modifications requested are attached.
101580	The committee voted 9-0 to require modifications to secure approval. The modifications requested are attached.
101574	The committee voted 9-0 to require modifications to secure approval. The modifications requested are attached.

F. Compliance Activities

- 1. Follow-up. None.
- 2. New. None.

VII. OTHER BUSINESS

- A. The committee voted 9-0 to approve the proposed changes to the Policy on the Review of Animal Use Protocols.
- **B.** The committee discussed Occupational Health and Safety Program compliance during and post COVID campus shut down.

VIII. NEXT MEETING

The December meeting is cancelled. The next IACUC meeting is scheduled for January 7, 2021 at 3:00 pm via videoconference. The meeting deadline is December 16, 2020.

IX. ADJOURN The meeting was adjourned at 3:56pm.

Protocol Review Comments Summary Report Reference Number 101354 **Review Summary**

Animals and Procedures Section: Question: Procedure Description If an incision is made under anesthesia, this constitutes a non-survival Comments: surgery, not exsanguination under anesthesia.

Section	n: Altern	atives and Duplication
	Question:	Consideration of Alternatives
	Comments:	Please update the search to include the requested changes.
	Question:	Verification that Studies are not Duplicative
	Comments:	Please update the search to include the requested changes.
Section	n: Princi	pal Investigator's Assurance
	Question:	Principal Investigator's Assurance Statement
	Comments:	This assurance must be signed by the PI of record for all submissions.

Protocol Review Comments Summary Report Reference Number 101355 Review Summary

Section: Administrative

Ouestion: Protocol Associates

Comments: 1. The associate, [associate], must set up an AALAS Learning Library account and complete the required online training.

2. The associate, [associate], has not completed the required AALAS modules for surgery, as required under IACUC policy. They have been assigned.

3. The PI is described as overseeing all procedures but is not listed in surgical personnel. Please add the PI to surgical personnel and complete the section.

4. The associates, [4 associates], are described as being responsible for "all procedures" but not all the procedures are listed in their "responsibilities" section, and they are not listed in surgical personnel. Please be specific in the "responsibilities" section for all associates.

5. [Associate] is described as providing training for several associates. Trainers must be added to the protocol, in both this section and the Surgical personnel section.

6. There are 2 species listed for this protocol, but it is unclear which associates are working with which species (or both). Please specify which species and procedures each associate will work, their experience with that species and its procedures.

Section: Study Objectives

Question: Lay Summary

Comments: 1. This summary is not understandable to a layperson and needs to be rewritten. It is too technical for a high-school level of understanding.

2. This summary appears to be a combination of lay summaries from separate studies. Please provide a brief project overview and focus on the purpose of the amendment.

Section: Animals and Procedures

Question: Procedure Description

Comments: Will associates aspirate prior to injecting the drug to make sure the needle is not positioned in the bladder or intestines? Please clarify.

Question: Duration and Frequency of the Procedure

Comments: What is the frequency of IP injection for each rat? How many injections will be performed per animal?

Question: Procedure Description

Comments: Why are two anesthetic regimens being used? Isoflurane is recommended for the entire procedure. Please clarify.

Question:Duration and Frequency of the ProcedureComments:If the procedure is terminal, please indicate the frequency as once per rat.

Question: Procedure Description

Comments: Why are two anesthetic regimens being used? Isoflurane is recommended for the entire procedure. Please clarify.

Question:Animal Number JustificationComments:Should the number be 210 new mice, 198 for experiments and 12 forbreeding? Please clarify.

Question:Transfer InformationComments:Please include the strains being transferred from each protocol.

Question: Procedure Description

Comments: 1. Please replace "patient's skin" with "Rat's skin."

2. Please correct the second to last sentence with "sacrifice," not "scarify."

Question: Surgical Personnel Experience

Comments: 1. Please give more information for all associates regarding their experience with the species.

2. For [associate], please give more information regarding where and when they gained experience with the procedure.

3. For [2 associates], please give more information regarding where, when, and by whom they will be trained for this procedure. The individual training them should also be listed here.

Question:Hazardous AgentsComments:Please select "human tissues" and complete the fields below.

Section: Tumors, Cells, Antibodies, and Biologics

Question: Exemption Explanation

Comments: How do we know that infections will not be passed from human skin samples to the permissive, immunocompromised mice?

Section: Alternatives and Duplication Question: Rationale for Animal Use Comments: Please update this section to include the rationale for animals used for the amended procedure.

Question:Consideration of AlternativesComments:Please update this section to include the new procedures and agents.

Question: Verification that Studies are not Duplicative

Comments: Please update this section to include the proposed amendments.

Protocol Review Comments Summary Report Reference Number 101586 Review Summary

Section: Administrative

Question:Principal InvestigatorComments:PIs must be UofSC faculty with vertebrate animal research experience.Please name a UofSC faculty member as the PI for this protocol.

Question: Protocol Associates

Comments: The associate, [associate], must register for an AALAS Learning Library account and take online training as outlined by IACUC policy. Please contact [Fiscal Technician and phone number] or [IACUC Specialist and phone number] for assistance.

Section: Study Objectives

Question: Lay Summary
Comments: 1. The language used is understandable to a layperson but the importance to the animal or human health is not clearly defined.
2. The first sentence should provide more information on Juncoes. Is this species endangered?

Section: Animals and Procedures

Question:Description of Experimental DesignComments:Please briefly describe the collection of rectrices.

Question:RestraintComments:Please select "yes" since the animals will be more than momentarilyrestrained while captured.

Section: Field Studies

Question:PermitsComments:Please attach all permits here.

Question: Method of Capture- Live Capture and Release Comments: How many hours per day are the nets mounted and monitored, and for how many days?

Question:Euthanasia in the Event of Injury or Illness- Live Capture and ReleaseComments:Please describe the administration of isoflurane in the field.

Section: Alternatives and Duplication

Question:Consideration of AlternativesComments:Per the section instructions, please provide details of a database search todocument that alternatives don't exist.

Section: Principal Investigator's Assurance

Question: Principal Investigator's Assurance Statement

Comments: All submissions must be signed by the PI of record, who must be full-time faculty. Please have the USC faculty PI sign all subsequent submissions.

Protocol Review Comments Summary Report Reference Number 101583 Review Summary

Section: Administrative
Question: Protocol Associates
Comments: 1. For [associate], please describe her experience with the species and procedures. The details given regarding her training are described well.
2. Subcutaneous injection is described for both associates but is not listed as a procedure on this protocol. Please clarify.
3. Retro Orbital bleeding is listed as a procedure on this protocol but is not included for either associate's responsibilities. Please clarify.

Section: Animals and Procedures

Question: Transfer Information

Comments: This protocol has expired. Please update to include a current AUP.

Question: Description of Experimental Design
Comments: 1. Please limit weight loss to 15% or justify why 20% is necessary.
2. Please describe how weight loss will be monitored, as well as the frequency of monitoring.

Question:Food and/or Water Restriction DescriptionComments:Please reference adherence to the attached SOP.

Section: Alternatives and Duplication

Question: Rationale for Animal Use

Comments: Per the section instructions, please describe the rationale for using the specific strains of mice requested.

Protocol Review Comments Summary Report Reference Number 101580 Review Summary

Section: Study Objectives

Question: Lay Summary Comments: This summary is understandable to a layperson and the benefit to human health is understandable. It would be helpful to understand better how the study will be conducted and what animals will be used.

Animals and Procedures Section: Question: Strains not Listed Please delete the strain here and select from the list above. Comments: Animal Number Justification Ouestion: Comments: The flowchart contains group sizes of 10, 20, and 30. Please provide details of the power analysis that supports these group sizes. Description of Experimental Design Question: 1. Please limit weight loss to 15% or justify the larger percentage Comments: requested. 2. How are bacteria introduced for colonization experiments? Question: Procedure Description Comments: Please provide details on the "heat mat". How will temperature be monitored to ensure it is not too hot? Ouestion: **Procedure Description** Please describe what precautions will be taken to confirm placement of the Comments: injector in the stomach. Will a small amount of fluid be injected immediately prior to the full injection to confirm placement (by confirming lack of distress in the mouse)? Please clarify. Question: Procedure Description Please list a maximal volume of 1 ml or less and aspirate before injecting. Comments: Question: Procedure Description Comments: If blood draw results in more significant bleeding, how will this be handled? Ouestion: Food and/or Water Restriction Description Comments: Please reference adherence to the attached SOP. Alternatives and Duplication Section: Rationale for Animal Use Ouestion:

Comments: Please include each strain of mice used and the rationale for its use.

Protocol Review Comments Summary Report Reference Number 101574 Review Summary

Section: Administrative

Question: Protocol Associates

Comments: 1. For the associates [6 associates], please describe when their training is expected to take place. PIs are responsible for maintaining documentation of training for 3 years.

2. The procedures Tissue Collection, IP Inj, and Retro-Oribital BW are described but are not listed as a procedure on this protocol. Please review for congruency.

3. The procedures Admin. Special Diet, Bone Marrow Trans., and Rotorod Testing are listed as procedures on this protocol but are not described in any associate responsibilities. Who will perform these procedures?

4. [Associate]'s description of responsibilities is insufficient. Please be specific about what aspects of the protocol she will be assisting in.

5. [PI] is described as providing training for colon distention, but no other associate is listed as performing this procedure. Who will she train?

6. [PI] is described as continuing training under [associate] who is not listed on this protocol. Please add him here and in surgical associates as providing training. Also, please submit documentation of previous training for this procedure to the IACUC at <u>iacuc@mailbox.sc.edu</u>.

7. [PI] has an AALAS module, Pain Management in Laboratory Animals, assigned 11/2/20, to complete.

Section: Study Objectives

Question: Lay Summary

Comments: While this study is understandable to a layperson overall and the benefit to human health is shown, it would be better understandable if simplified and/or shortened. The experimental information can be omitted as it does not contribute to the understanding of a layperson.

Section: Animals and Procedures

Question: Category E Justification

Comments: Viscero-response to colorectal distension is Category E.

Question: Animal Number Justification

Comments: The initial description of the study power (and associated n) doesn't align with list provided. The justification provided is for 30 mice per group, but the experiments have group sizes of 10 and 20. Please provide a justification for the group sizes proposed. If n=10 (or 20), does that mean 5 of each sex or 10 males and 10 females?

Question: Description of Experimental Design

Comments: 1. Please elaborate on the postoperative portion of the protocol. How long will the animals have wires exposed? How will wound management be accomplished? How will they be monitored? What would necessitate removal from the study?
2. This section contains over 4000 words; it must be revised to fewer than 1500 words as per the section instructions. Experimental details can be removed from this section and provided in the appropriate procedure section below.

Question:ProceduresComments:IP injections and tissue collection after euthanasia must be added and thesections filled out.

Question: Location Comments: This procedure is described below as being performed in a laboratory room. Please review for congruency.

Question: Location Comments: This procedure is described below as being performed in a lab, not an animal room. Please review for congruency.

Question: Location

Comments: The procedure is described below as being performed in a laboratory. Please review for congruency.

Question:Procedure DescriptionComments:[2 rooms] are not animal rooms. Please review location of this procedurefor congruency.

Question:Survival Surgical ProceduresComments:Please select the surgical procedure(s) and complete the section(s).

Question:Survival Surgery LocationComments:Surgeries cannot be performed in animal rooms. Please select anappropriate location.

Question:Surgical PreparationComments:Complete the section.

Question:Food and/or Water Restriction DescriptionComments:Complete the section.

Question:Food and/or Water Restriction JustificationComments:Complete the section.

Question: Housing Description

Comments: Please describe and justify how the animals will be housed, and how it varies from the above attached SOPs and IACUC policy. Include how the cages will be marked to notify DLAR staff of the housing exemption.

Question:Personal Protective EquipmentComments:Complete the section.